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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,904	03/31/2004	Iain H. Kalfas	101896-366 (DEP5181)	5037

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EXAMINER	
YANG, ANDREW	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
08/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/813,904	KALFAS ET AL.	
	Examiner	Art Unit	
	ANDREW YANG	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-35,56,57 and 60-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-35,56,57 and 60-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/18/2008, 5/13/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicants' amendment filed on May 6, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-11, 15-20, 29, 56, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816).

Gelbard discloses a spinal stabilization system with a plurality of bone anchors 12, a rod 28 connecting at least two bone anchors 12, and a connecting plate 36 extending from a proximal surface of the bone anchors 12. The bone anchors 12 are monoaxial and have a distal portion 16 and a rod-receiving portion 26 that defines the proximal surface. The connecting plate 36 has openings 42 at a first end 38 and openings 44 at a second end 40 for attachment to the bone anchor and a spanning portion extending connecting the first end 38 to second end 40 (Figure 1). Furthermore, the plate 36 and rod 28 are oriented at an angle of about 90 degrees (Figure 1).

With reference to Figure 1, the device is used to fix vertebrae by attaching a plurality of bone anchors into adjacent vertebra. More specifically, a pair of anchors 12 is attached to a first vertebra, and a second pair of anchors 12 is attached to a second

vertebra. The anchors 12 that are not attached to the same vertebra are connected by rod 28 and the anchors 12 that are attached to the same vertebra are connected by plate 36.

Gelbard discloses the claimed invention except for the connecting plate bearing against a terminal end surface of the opposed arms of the rod receiving portion and a set screw threadingly engaging the rod receiving portion and a cap that threadingly engages the set screw and a buttress at a distal side of the spanning portion. Dinello teaches a spinal corrective device with members 34, rods 10, and a connecting plate 30. The members 34 have a rod-receiving portion 40 and an opening 46 for receiving a set screw 48. Set screw 48 is used to clamp the rod against surface 42 of the rod-receiving portion 40. The plate 30 with openings 56 at each end and are placed over the set screw 48 and engaging a proximal terminal end of member 34. The plate 20 is then engaged by a cap 74 to clamp the plate 30 to members 34. The plate 30 also has buttress portions 58 at a distal end of the plate and is in place for preventing the plate 30 from pivoting relative to the members 34 (Column 3, Lines 15-19). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard with a set screw threadingly engaging the rod receiving portion, a cap to engage the set screw, and a buttress at an end of the plate in view of Dinello et al. in order to clamp the rod and plate to the members which they contact, and also to prevent the plate from pivoting relative to the member it is connected to. Furthermore, it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard with the plate engaging a proximal terminal end of the

rod receiving portion in view of Dinello et al. Using the known technique of providing a connecting plate along a proximal terminal end surface of a rod engaging member as taught by Dinello et al. would have been obvious to one skilled in the art.

With regard to claim 16, Dinello et al. discloses the set screw engaging a bore defined by the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a cap that engages a threaded bore defined by the set screw, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

With regard to claims 9-11, Gelbard fails to disclose the connecting plate having a distal bearing surface that is domed with a spherical or conical shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the distal bearing surface of the connecting plate have a distal bearing surface that is domed, with a spherical or conical shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing two distal bearing surfaces. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 12-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816) and further in view of Bono et al. (U.S. Publication No. 2004/0087949).

Gelbard and Dinello et al. disclose the claimed invention except for a floating washer with a bearing surface that mates with the distal bearing surface of the cap, and

rails that slidably engage the connecting plate. Bono et al. teaches a spinal fixation system with a plate 1 having a bone anchor portion 10 and a washer 30. Washer 30 has projections 34 which are for engaging channels 14 of the bone anchor portion 10. (Paragraph 32). A bone anchor can then be placed through the hole 32 of the washer, and by use of locking nut is held by compression between the washer and the bone anchor (Paragraph 30). The washers of the assembly minimize the number of parts a surgeon may have to handle during surgery (Paragraph 29). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard in view of Dinello et al. with a floating washer having rails that slidably engage the connecting plate further in view of Bono et al. in order to minimize the number of parts a surgeon ahs to handle during surgery.

Claims 30-35, 57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816) and further in view of Mathis et al. (U.S. Publication No. 2004/0186474).

Gelbard and Dinello et al. disclose the claimed invention except for using polyaxial screws that have a radius of curvature about a point which the bone screw pivots for the bone anchors. Mathis et al. teaches an implant for use in spinal surgery that uses a polyaxial screw with a spherical head 2, held in rod receiving portion 3. The head has a radius of curvature about a point which the bone screw pivots. The used of the polyaxial screw is so that the angular position of the screw can be changed relative to the receiver portion 3 (Paragraph 38). It would have been obvious to one skilled in

the art at the time the invention was made to construct the device of Gelbard as modified by Dinello et al. with bone anchors that are polyaxial screws further in view of Mathis et al. so that the angular position of the bone anchors could be adjusted.

With regard to claim 35, Mathis et al. teaches a compression element 10 for fixation of the angular position of the polyaxial screw. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard as modified by Dinello et al. with a polyaxial screw with a compression member further in view of Mathis et al. so that the angular position could be fixed.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816) and further in view of Dove et al. (U.S. Patent No. 5366455).

Gelbard and Dinello et al. disclose the claimed invention except for a plate that has a spanning member that is arcuate in shape and a hole that is circular or elliptical in shape. Dove et al teaches a spinal fixation device with bone anchors 29, a rod 26, and a plate 10. The plate has a spanning portion 11 that is curved and is also offset from a planed defined by the end 13 of the plate 10 to allow clearance for the spinous processes (Column 2, Lines 62-65) and a hole 14 that is substantially elliptical (Figure 2) to receive a screw (Column 2, Lines 42-44). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard as modified by Dinello et al with a curved spanning portion and an elliptical hole further in view of Dove et al. so that the plate will have clearance for the spinous processes and to receive screws..

With regard to the radius of curvature and the distance that the spanning portion is offset from the end of the plate, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spanning portion of Gelbard with a radius of cuvature between 8mm and 12mm or 5mm and 15mm and offset at least 3mm and between about 5mm and 10mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbard (U.S. Patent No. 5397363) in view of Dinello et al. (U.S. Patent No. 5522816) and further in view Dove et al. (U.S. Patent No. 5366455) and further in view of Pisharodi (U.S. Patent No. 6355038).

Gelbard, Dinello et al. and Dove et al. disclose the claimed invention except for the opening of the connecting plate being open ended. Pisharodi teaches a spinal fixation assembly with a plate 32 having an open-ended hole 44 for facilitating assemble of the plate 32 to screws 34. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gelbard as modified by Dinello et al and Dove et al. with a plate having a hole with an open end further in view of Pisharodi in order to facilitate assemble of the plate to the bone anchors.

Response to Arguments

In response to Applicants' argument that it would not have been obvious to combine the references of Gelbard and Dinello et al., the Examiner respectfully disagrees. Both Gelbard and Dinello et al. disclose devices which secure both a rod and a plate within the same anchoring device. Gelbard uses a plate fitted onto opposing arms held in place with a nut. Dinello et al. discloses a plate fitted on the top surface of an anchor which is held in place with a set screw and a nut. One skilled in the art would have found it obvious to try such an arrangement with the device of Gelbard since both references teach similar devices with only the means of holding the plate and rod to be different. Furthermore, the plate and locking mechanism of Dinello et al. offers the advantage of having the plate to be adjustable. Furthermore, the device of Gelbard as modified by Dinello et al. would have a closure mechanism (48) that engages the bone anchor.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3733
8/5/2008

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733